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510(k) Premarket Notification Summary of Safety and Effectiveness Information	***Wristore Fixator*** ***December 14, 2001***

Device Name:
Trade Name: ***Wristore Fixator***
Common Name: External Fixator
Classification Name: Single/multiple component metallic bone fixation appliance and accessories.

Establishment Name & Registration Number:
Name: Millennium Medical Technologies, Inc.
Number: Pending

Classification:
§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) Identification. Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system. (b) Classification. Class II.

Device Class: Class II for all requested indications.

Classification Panel: Physical Medicine Devices Panel

Product Code: 87KTT/HRS

Substantially Equivalent Device(s):
Millennium Medical Technologies, Inc. believes that the ***Wristore Fixator*** is substantially equivalent to the following legally marketed upper extremity external fixators marketed by DePuy, Inc and Synthes, Inc. respectively.

- ***K003397***, Colles C Series Frame Sterile Pack.
- ***K984498***, Articulating Distal Radius Fixator.

Both referenced equivalent fixators are legally marketed. Both fixators have the same indications for use as the ***Wristore*** and, in the case of the Synthes fixator, is made from the identical material. All three systems utilize the same type of fixation pins. All three systems are clinically equivalent in terms of design, materials, indications, cautions, precautions and adverse events. A feature comparison chart is included at the end of the summary that graphically depicts substantial equivalence.

Description of the Device:
The materials utilized for the construction of the external elements of the ***Wristore Fixator*** are medical grade polyetherimide resin. This material is the identical material utilized to construct the Articulating Distal Radius Fixator (K984498). The materials utilized in the instruments and pin guides are instrument grade stainless steel. The pins and K-wires used to fix the fractured bones are produced from implant grade stainless steel (316L). The ***Wristore Fixator*** utilizes legally marketed commercially available fixation pins and/or K-wires. Once the provided K-wires and pins have been properly placed, the poly-resin external frame is tightened and the fracture(s) stabilized. Typical orthopaedic instrumentation is provided to place, tighten and adjust the fixator.

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Each *Wristore Fixator* is supplied with:

1. Main Body Fixator
2. Radial Triangle
3. Double K-wire Clamp (up to 1.0mm)
4. Single K-wire Clamp
5. Universal Inserter – stainless steel
6. Pin Guide - stainless steel
7. K-wires – 316L SS, 0.08, 3 each
8. Threaded Half Pins - 316L SS, (2.5, 3.0, 3.5 & 4.0mm) 4 each.

The ***Wristore Fixator*** is supplied with standard, commercially available orthopaedic instruments. No proprietary or specialized instruments are needed to use the system.

Sterilization, Packaging and Storage:
The ***Wristore Fixator*** is supplied NON-STERILE. The ***Wristore Fixator*** and instruments must be sterilized before use. The device is supplied clean and has been processed to remove debris and manufacturing residue. Before using, all labels and packaging materials must be removed and the device and instruments thoroughly washed before sterilization and use. Cleaning and rinsing should be conducted in accordance with accepted hospital practice using hot water and a commercial instrument detergent or soap. Once cleaned, the ***Wristore Fixator*** may be sterilized according the following validated steam sterilization cycle:

Saturated steam at 250° F for 30 minutes. This cycle will provide a Sterility Assurance Level (SAL) of at least 10^{-6}. Validation of the recommended cleaning protocol and sterilization cycle is complete. Validation was achieved in accordance with a modified AAMI ST32 Method 3, Protocol B as recommended by the biological testing laboratory. Validation for the following cycle is on file at Millennium Medical Technologies, Inc.:

Method:	Steam
Cycle:	Gravity
Temperature:	250° F (121° C)
Exposure Time:	30 minutes

Applicant / Sponsor Name / Address:
Millennium Medical Technologies, Inc.
460 St. Michaels Drive, Suite 901
Santa Fe, New Mexico, 87505
505.988.7595 – 505.988.7234 fax

Contact Person:
Mr. Fred Kolb
Millennium Medical Technologies, Inc.
460 St. Michaels Drive, Suite 901
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Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 / 925.356.2654 FAX

Manufacturing Facility:
At the present time, the ***Wristore Fixator*** is manufactured under contract for Millennium Medical Technologies, Inc.

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Feature Comparison Table:

FEATURE	*Wristore Fixator*	*DePuy Colles C series frame*	*Synthes USA – Articulating Distal Radius Fixator*	SE?
Intended Use:	Colles, mid & proximal fractures of the upper extremity	Same	Same	Yes
Design:	Single frame, transfixing pin based external fixator	Same	Same	Yes
Supplied Sterile:	No	Yes	Yes	No
Single Use:	Yes	No	Yes	Yes
Sterilization Method:	Steam	Unknown	Unknown	???
Materials:	Polyethermide resin, stainless steel	Metallic	Polyethermide resin, stainless steel	No/ Yes
Product Code:	KTT/HRS	KTT	HRS	Yes
K-Number	***K012294***	***K003397***	***K984498***	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Millenium Medical Technologies, Inc
c/o Mr. David Schlerf
Buckman Company, Inc
200 Gregory Lane Suite C-100
Pleasant Hill, California 94523-3389

Re: K012294
Trade Name: Wristore Fixator
Regulatory Number: 888.3030 and 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories; and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: KTT and NDK
Dated: December 14, 2001
Received: January 24, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

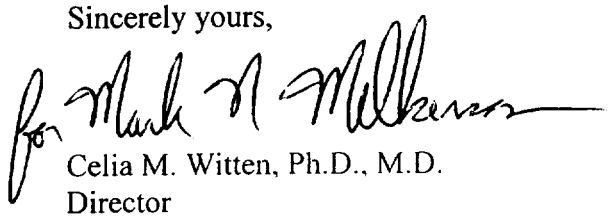
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012294

Device Name(s): ***Wristore Fixator***

Intended Use(s) of the Device:

The ***Wristore Fixator*** is intended to provide external fixation of the upper extremity. External fixation devices allow for three plane (axial, AP & medio/lateral) control over fractures and bone segments.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012294

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional format 1-2-96)